K122595

DERMAL LIFE
Advanced Skin Care Solutions

510(k) Summary of Safety and Effectiveness

MAY 0 1 2013

HYDROPERMEATE™ Topical Emulsion

Manufacturer and Submitter

Company Name:	Dermal Life LLC
Company Address:	13046 Race Track Rd. Tampa, FL 33636 Telephone: 317.669.2229
Contact Person:	William R. Hitchens
Date Summary Prepared:	August 24, 2012

Device

Trade/Device Name:	Dressing, Wound, Drug
Common/Usual Name:	Wound Dressing Containing Drug
Classification Name:	Unclassified
Regulation Number:	Unclassified
Product Code:	FRO
Classification Panel:	General & Plastic Surgery
Classification:	Unclassified

Substantial Equivalence

This 510(k) submission demonstrates that HYDROPERMEATE™ Topical Emulsion is substantially equivalent to BIAFINE™ Wound Dressing Emulsion (K964240) in both technology and intended use.

Device Description

HYDROPERMEATE™ Topical Emulsion consists of approximately 75% purified water, 20% wax (oily) ingredients, and 5% of dissolved ingredients such as triethanolamine sodium alginate, which forms a gel with water. HYDROPERMEATE™ is a prescription product.

Indications for Use

The prescription product requires a physician's diagnosis and is indicated as follows:

HYDROPERMEATE™ Topical Emulsion is indicated for use in:

- Full thickness wounds, pressure sores, dermal ulcers including lower leg ulcers
- Superficial wounds
- 1st and 2nd degree burns, including sunburns
- Dermal donor and graft site management
- Radiation dermatitis
- Minor abrasions

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Summary of Technological Characteristics of the Device Compared to Predicate Device

HYDROPERMEATE™ Topical Emulsion is technologically similar to the predicate device. The Dermal Life product was tested for performance criteria (physical parameters, biocompatibility, human dermal studies for irritation and dermal sensitization). Performance data support that the Dermal Life wound dressing meets its specified criteria.

Conclusion

Functional and performance testing has been conducted to assess the safety and efficacy of HYDROPERMEATE™ Topical Emulsion and the results support the substantial equivalence to the predicate device.

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510(k) Summary of Safety and Effectiveness

ANSWER2SKIN™ SUNBURN RELIEF Cream
ANSWER2SKIN™ FIRST AID Cream

Manufacturer and Submitter

Company Name:	Dermal Life LLC
Company Address:	13046 Race Track Rd. Tampa, FL 33636 Telephone: 317.669.2229
Contact Person:	William R. Hitchens
Date Summary Prepared:	August 24, 2012

Device

Trade/Device Name:	Dressing, Wound, Drug
Common/Usual Name:	Wound Dressing Containing Drug
Classification Name:	Unclassified
Regulation Number:	Unclassified
Product Code:	FRO
Classification Panel:	General & Plastic Surgery
Classification:	Unclassified

Substantial Equivalence

This 510(k) submission demonstrates that ANSWER2SKIN™ SUNBURN RELIEF Cream, and ANSWER2SKIN™ FIRST AID Cream are substantially equivalent to BIAFINE™ Wound Dressing Emulsion (K964240) in both technology and intended use.

Device Description

ANSWER2SKIN™ SUNBURN RELIEF Cream, and ANSWER2SKIN™ FIRST AID Cream are topical emulsions consisting of approximately 75% purified water, 20% wax (oily) ingredients, and 5% of dissolved ingredients such as triethanolamine sodium alginate, which forms a gel with water. ANSWER2SKIN™ SUNBURN RELIEF Cream, and ANSWER2SKIN™ FIRST AID Cream are over-the-counter products.

Indications for Use

ANSWER2SKIN™ SUNBURN RELIEF Cream is intended to be used Over-the-Counter as a wound dressing for the following indications: minor burns, including minor sunburns.

ANSWER2SKIN™ FIRST AID Cream is intended to be used Over-the-Counter as a wound dressing for the following indications: minor superficial wounds and minor abrasions, including cuts and scrapes.

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Summary of Technological Characteristics of the Device Compared to Predicate Device

ANSWER2SKIN™ SUNBURN RELIEF Cream, and ANSWER2SKIN™ FIRST AID Cream are technologically similar to one another and also to the predicate device. The Dermal Life products were tested for performance criteria (physical parameters, biocompatibility, human dermal studies for irritation and dermal sensitization). Performance data support that the Dermal Life wound dressings meet its specified criteria.

Conclusion

Functional and performance testing has been conducted to assess the safety and efficacy of ANSWER2SKIN™ SUNBURN RELIEF Cream, and ANSWER2SKIN™ FIRST AID Cream and the results support the substantial equivalence to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Dermal Life LLC
% Diane Horwitz, Ph.D., RAC
Mandell Horwitz Consultants LLC
2995 Steven Martin Drive
Fairfax, Virginia 22031

May 1, 2013

Re: K122595
Device Name: Hydropermeate Topical Emulsion, Answer2skin Sunburn Relief Cream and Answer2Skin First Aid Cream
Regulation Name: Wound Dressing with Drug
Regulatory Class: Unclassified
Product Code: FRO
Dated: March 14, 2013
Received: March 15, 2013

Dear Dr. Horwitz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K122595

Device Name: HYDROPERMEATE™ Topical Emulsion

Indications For Use:

HYDROPERMEATE™ Topical Emulsion is intended to be used as a wound dressing for the following indications:

- Full thickness wounds, pressure sores, dermal ulcers including lower leg ulcers
- Superficial wounds
- 1st and 2nd degree burns, including sunburns
- Dermal donor and graft site management
- Radiation dermatitis
- Minor abrasions

Prescription Use __X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jiyoung Dang -S

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K122595

Indications for Use

510(k) Number: K122595

Device Name: ANSWER2SKIN™ SUNBURN RELIEF Cream and ANSWER2SKIN™ FIRST AID Cream

Indications For Use:

ANSWER2SKIN™ SUNBURN RELIEF Cream is intended to be used Over-the-Counter as a wound dressing for the following indications: minor burns, including minor sunburns.

ANSWER2SKIN™ FIRST AID Cream is intended to be used Over-the-Counter as a wound dressing for the following indications: minor superficial wounds and minor abrasions, including cuts and scrapes.

Prescription Use _____ AND/OR Over-The-Counter Use __X___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jiyoung Dang -S

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K122595